

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OF PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A hydrostatic delivery system comprising a hydrostatic couple and an agent of interest.
2. The hydrostatic delivery system of claim 1 wherein said hydrostatic couple comprises, at least one hydrodynamic fluid-imbibing polymer, and at least one hydrostatic pressure modulating agent.
3. The hydrostatic delivery system of claim 2, wherein said hydrodynamic fluid-imbibing polymer is a cross-linked polymer having a swell capacity in a fluid environment of between about 1 weight% to about 3000 weight%.
4. The hydrostatic delivery system according to claim 3, wherein said cross-linked polymer is present from about 4 weight% to about 96 weight% of the total formulation.
5. The hydrostatic delivery system according to claim 2, wherein said hydrostatic pressure modulating agent is a cross-linked, rapidly swelling polymer having a swell capacity in a fluid environment of between about 0.5 weight% to about 500 weight%.
6. The hydrostatic delivery system according to claim 5, wherein said cross-linked polymer present from about 0.5 weight% to about 50 weight% of the total formulation.
7. The hydrostatic delivery system according to claim 2, wherein said hydrostatic pressure modulating agent, further comprises an expansion source.
8. The hydrostatic delivery system according to claim 7, wherein said expansion source is selected from the group consisting of a carbon-dioxide precursor, an oxygen precursor, and a chlorine dioxide precursor.
9. The hydrostatic delivery system according to claim 3, wherein said hydrodynamic polymer and said hydrostatic pressure modulating agent are present at a ratio from about 99:1 to about 50:50 by weight.
10. The hydrostatic delivery system according to claim 3, wherein said hydrodynamic polymer is a carbon dioxide precursor, an oxygen precursor or a chlorine dioxide precursor, said hydrodynamic polymer and said hydrostatic pressure modulating agent present in a ratio from about 99:1 to about 70:30 by weight.

SUB
AIP

11. The hydrostatic delivery system according to claim 1 wherein the agent of interest comprises a plurality of discrete active particulates.

12. The hydrostatic delivery system according to claim 2, wherein said hydrodynamic fluid-imbibing polymer comprises one or more of the compounds selected from the group consisting of:

- i) an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol;
- ii) one or more starch derivatives cross-linked by Epichlorhydrin, Phosphorous oxychloride (POCl_3), or Sodium trimetaphosphate;
- iii) a polyglucan;
- iv) a crosslinked polyacrylate resin;
- v) a crosslinked polyethylenimine;
- vi) a crosslinked polyallylamine, and

combinations thereof.

13. The hydrostatic delivery system according to claim 2, wherein the hydrostatic pressure modulating agent comprises one or more of the compounds selected from the group consisting of:

- i) homopolymers of cross-linked N-vinyl-2-pyrrolidone;
- ii) a rapidly expanding cross-linked cellulose derivative; and

combinations thereof

14. The hydrostatic delivery system according to claim 12, wherein said acrylic-acid polymer is selected from a group consisting of Carbopol.RTM.971P, Carbopol.RTM.934P, Carbopol.RTM.971P, Carbopol.RTM. EX507, and a combination thereof.

15. The hydrostatic delivery system according to claim 14, wherein said acrylic-acid polymer has a viscosity from about 3,000 centipoise to about 45,000 centipoise at 0.5% w/w concentration in water at 25°C.

16. The hydrostatic delivery system according to claim 15, wherein said acrylic-acid polymer has a primary particle size range from about 3.00 to about 10.00 microns in diameter.

17. The hydrostatic delivery system according to claim 12, wherein said polyglycan is selected from the group consisting of amylose, dextran, pullman

succinate containing diester or diether crosslinks, pullman glutarates containing diester or diether crosslinks, and a combination thereof.

18. The hydrostatic delivery system according to claim 13, wherein said homopolymers of cross-linked N-vinyl-2-pyrrolidone are selected from the group consisting of Polyplasdone.RTM.XL, Polyplasdone.RTM. XL-10, Polyplasdone.RTM. INF-10, and a combination thereof.

19. The hydrostatic delivery system according to claim 16, wherein said cross-linked N-vinyl-2-pyrrolidone has a particle size from about 9 microns to about 150 microns.

20. The hydrostatic delivery system according to claim 13, wherein said rapidly swelling cross-linked cellulose derivative is selected from the group consisting of cross-linked carboxymethyl cellulose, sodium starch glycolate, and a combination thereof.

21. The hydrostatic delivery system according to claim 8, wherein said carbon dioxide precursor is selected from the group consisting of carbonates, sesquicarbonate, hydrogencarbonate, potassium carbonate, lithium carbonate, sodium carbonate, ammonium carbonate, sodium amino acid carbonate, sodium glycine carbonate, L-lysine carbonate and arginine carbonate.

22. The hydrostatic delivery system according to claim 8, wherein said oxygen precursor is selected from the group consisting of sodium percarbonate, sodium perborate monohydrate, anhydrous sodium perborate, effervescent perborate, and sodium dichloroisocyanurate.

23. The hydrostatic delivery system according to claim 8, wherein said chlorine dioxide precursor is selected from the group consisting of sodium hypochlorite and calcium hypochlorite.

24. The hydrostatic delivery system according to claim 2 wherein the dosage form is a multiparticulate matrix tablet, or capsule.

25. The hydrostatic delivery system according to claim 2 further comprising an enteric coating or one or more pH sensitive barrier polymers.

26. The hydrostatic delivery system according to claim 2, wherein the agent of interest is selected from the group consisting of analgesic, anti-inflammatory, antimicrobial, amoebicidal, trichomonocidal agents, anti-parkinson, anti-malarial,

anticonvulsant, anti-depressants, antiarthritics, anti-fungal, antihypertensive, antipyretic, anti-parasite, antihistamine, alpha-adrenargic agonist; alpha blocker , anesthetic, bronchial dilator, biocide, bactericide, bacteriostat, beta adrenergic blocker, calcium channel blocker, cardiovascular drug, contraceptive, decongestants, diuretic, depressant, diagnostic, electrolyte, hypnotic, hormone, hyperglycemic, muscle relaxant, muscle contractant, ophthalmic, parasympathomimetic, psychic energizer, sedative, sympathomimetic, tranquilizer, urinary, vaginal, viricide, vitamin, non-steroidal anti-inflammatory, angiotensin converting enzyme inhibitors, polypeptide, proteins, and sleep inducers.

27. The hydrostatic delivery system of claim 2 further comprising one or more pharmaceutical excipients including but not limited to viscosity enhancer(s), enteric polymer(s), pH-specific barrier polymer(s), diluent(s), anti-adherent(s), glidant(s), binder(s), solubilizer(s), channeling agent(s), wetting agent(s), buffering agent(s), flavorants, adsorbents, sweetening agent(s), colorant(s) and lubricant(s).

28. The hydrostatic delivery system of claim 2 further comprising an adjuvant.

29. The hydrostatic delivery system of claim 2, wherein said hydrostatic delivery system is a matrix-type solid compact, made by a compression or pelletization method.

30. The hydrostatic delivery system of claim 2, wherein said hydrostatic delivery system is a matrix-type extrusion spheroid, made by a wet or dry extrusion method.

31. The hydrostatic delivery system of claim 2, wherein said hydrostatic delivery system is granulated or microencapsulated to form particulates that may be compressed into solid compacts or filled into capsules.

32. The hydrostatic delivery system of claim 2, wherein said hydrostatic delivery system is selected from the group consisting of granulated, particulate, spheroidal, compact, and dry blends, said hydrostatic delivery system can be filled into a capsule or suspended in a suitable liquid vehicle.